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Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/533,895	09/26/95	TOPALIAN	S 2026-4205

18M1/0411

PATENT BRANCH  
OFFICE OF TECHNOLOGY TRANSFER  
NATIONAL INSTITUTES OF HEALTH BOX 13  
6011 EXECUTIVE BOULEVARD SUITE 325  
ROCKVILLE MD 20852

EXAMINER

CAPUTA, A

ART UNIT

PAPER NUMBER

1817

DATE MAILED:

04/11/97

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/533,895

Applicant(s)  
Toplian et al.

Examiner  
Anthony C. Caputa

Group Art Unit  
1817



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_ -- \_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-63 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-63 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 31-46, 62, and 63, drawn to a nucleic acid, classified in class 536, subclass 23.5.
  - II. Claims 1-30, 56, and 61 drawn to a peptide, tumor associated antigens or melanoma antigens, classified in class 530, subclass 326+.
  - III. Claims 47-51, drawn to an antibody, classified in class 530, subclass 387.9.
  - IV. Claims 57-60 drawn to a method of isolating class II tumor associated antigens, classified in class 530, subclass 412.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and IV drawn to a protein or peptide and Invention III drawn to antibodies are distinct since they are products with different structure and biological properties. The claimed antibody of Invention III is made up of F<sub>ab</sub> and F<sub>c</sub> fragments whereas the protein or peptide of Inventions II, and IV is not. Furthermore, the amino acid composition of the protein or peptide is distinct from amino acid composition of the antibody. Additionally, the Inventions are distinct since methods known in the art used to make the protein or peptide does not require the antibody. For instance, the protein or peptide can be made by Merrifield chemical synthesis or DNA.

Inventions II-IV drawn to protein (or antibodies) and Invention I drawn to DNA are distinct since they are products with different structure and biological properties. The claimed protein (or antibody) is made of amino acids whereas the claimed DNA are made of nucleotides. Furthermore, methods known in the art used to make the protein (or antibody) require different reagents and parameters from the methods of making DNA encoding the protein and the method of making the protein (or antibody) does not require the DNA. For instance, the protein can be

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made by Merrifield chemical synthesis or affinity chromatography which does not require the DNA.

Inventions IV and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by recombinant means, or Merrifield chemical synthesis.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application (Groups I-IV) contains claims directed to the following patentably distinct species of the claimed invention:

- A. Ty 56-70; Ty 57-70; Ty 56-70, L65→V; Ty 56-70, A63→V and L65→V; Ty 56-70, A63→V; and  $X_1LLX_2NX_3X_4LX_5$
- B. Ty 448-462; Ty 449-462; Ty 450-462; Ty 448-462, F460→S; Ty 448-462, Y449-Q; Ty 448-462, Y449→F; Y451→F; Ty 448-462, D456→V; and  $X_1LQX_2SX_3X_4DX_5$
- C. MART-1;
- D. gp100;
- E. gp-75;
- F. MAGE-1
- G. MAGE-2
- H. MAGE-3

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Species A-H are distinct since they are antigens with different structure (i.e. amino acid composition) and properties (i.e. antigenicity, immunogenicity)

Applicant is required under 35 U.S.C. 121 to elect a single species (e.g. species a, b, c, d, e, f, g, or h) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 57-69, and 61 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. A telephone call was made to Carol Gruppi to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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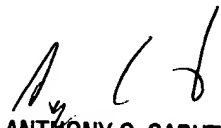
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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa whose telephone number is (703) 308-3995.

Anthony C. Caputa, Ph.D.

April 10, 1997

  
ANTHONY C. CAPUTA  
PRIMARY EXAMINER  
GROUP 1800